

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of:** Heinrich et al.**Application No.** 10/517,905**Filed:** December 10, 2004**Confirmation No.** 4619**For:** METHOD OF DETECTING A  
NEOPLASIA ASSOCIATED WITH AN  
ACTIVATING PLATELET DERIVED  
GROWTH FACTOR RECEPTOR ALPHA  
(PDGFRA) MUTATION**FILED VIA EFS****Examiner:** Zachary C. Howard**Art Unit:** 1646**Attorney Reference No.** 899-65892-02FILED VIA EFS  
COMMISSIONER FOR PATENTS**STATEMENT UNDER 37 C.F.R. § 1.702(b)(2)**

1. This statement is respectfully submitted in support of the "Petition for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. § 1.705(b)" for the above-referenced application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of 989 days, with an additional term to be added based on the number of days following payment of the issue fee on May 14, 2009, to the date of issuance of a patent for the above-referenced patent application.
2. The patent term adjustment on the Determination of Patent Term Adjustment Under 35 U.S.C. § 154(b) ("PTAS Sheet") that was attached to the Notice of Allowance is 469 days. Submitted herewith as Exhibit A is a copy of the Patent Term Adjustment History available on PAIR. This determination of 469 days is in error in that pursuant to 35 U.S.C. § 154(b) the Office failed to take certain action within the time frame specified in 37 C.F.R. § 1.702(a) and failed to issue a patent within three years of the actual filing date of the above-referenced application in accordance with 37 C.F.R. § 1.702(b).

Pursuant to 37 C.F.R. § 1.703(a), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than

14 months after the actual filing date (*i.e.*, by February 10, 2006) (hereinafter “14 Month Delay”). As the Office failed to mail an action under 35 U.S.C. § 132 until September 26, 2007, Applicants are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date on which the above-referenced application was filed under 35 U.S.C. § 111(a), *i.e.*, February 11, 2006, and ending on the date of the mailing of an action under 35 U.S.C. § 132, *i.e.*, September 26, 2007. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 593 days, which is in agreement with the period calculated by the Office as illustrated by Exhibit A.

In addition to the patent term adjustment due to the 14 Month Delay, pursuant to 37 C.F.R. § 1.703(b), Applicants are entitled to a period of a patent term adjustment due to examination delay from the number of days in the period beginning on the day after the date that is three years after the date on which the above-referenced application was filed under 35 U.S.C. § 111(a), *i.e.*, December 11, 2007, and ending on the date a patent is issued, (hereinafter “Three Years Delay”). As the issue date has yet to be determined, Applicants have calculated a minimum period of Three Years Delay of 520 days, based on a hypothetical issue date of May 14, 2009, the date on which the issue fee is paid. This delay is omitted by the Office on the PTAS Sheet.

As set forth in 37 C.F.R. § 1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays based on the grounds set forth in 37 C.F.R. § 1.702 reduced by the period of time equal to the period of time during which Applicants failed to engage in reasonable efforts to conclude prosecution pursuant to 37 C.F.R. § 1.704 (hereinafter “Applicant Delay”). Applicants delay consisted of 124 days as calculated by the USPTO (see Exhibit A).

Thus, with respect to the above-referenced application, the total period of examination delays is the sum of the period of 14 Month Delay (593 days) and the minimum period of Three Years Delay (520 days), or 1113 days, to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on September 26, 2007, prior to the first day of the

period of Three Years Delay, *i.e.*, December 11, 2007, Applicants submit that these periods are not overlapping.

To calculate the period of patent term adjustment, the total period of examination delay (1112 days) is reduced by the period of Applicant Delay, which the USPTO has calculated as a period of 124 days (see Exhibit A). Accordingly, Applicants submit that the correct patent term adjustment for the above-referenced application is **at least 989 days**, which is the difference between the total period of examination delay (1113 days) and the period of Applicant Delay (124 days). Applicants further submit that the term of 1113 days should be extended by an additional term equal to the number of days following payment of the issue fee on May 14, 2009 to the date of issuance of a patent for the above-referenced application in accordance with 37 C.F.R. § 1.703(b). **As such, the correct patent term adjustment upon issuance of a patent is expected to be the sum of 989 days (as calculated herein) plus the number of days from May 15, 2009, to issuance of a patent.**

3. The factual bases for the above adjustment are set forth as follows:

**A. Examination Delays Pursuant to 37 C.F.R. § 1.702 and § 1.703**

Pursuant to 37 C.F.R. § 1.703(f), the period of adjustment of the term of the patent under § 1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704 (the period of Applicant Delay). In the above-referenced application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under § 1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to § 1.703(a)(1)

In accordance with 37 C.F.R. § 1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than 14 months after the actual filing date (*i.e.*, by February 10, 2006). As shown in Exhibit A, the Office failed to mail an action under 35 U.S.C. § 132 until September 26, 2007 (when a Restriction Requirement was mailed). As such, Applicants are entitled to a period of patent term adjustment beginning February 11, 2006, and ending on September 26, 2007, the date of mailing of the Restriction Requirement by the Office. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 593 days, as is correctly shown on Exhibit A.

(ii) “Three Years Delay” Pursuant to 37 C.F.R. § 1.703(b)

It is anticipated that the Office will not comply with the requirement of 35 U.S.C. § 154(b) and 37 C.F.R. § 1.702(b), which requires issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. § 111(a). As indicated in the Notice of Allowance, a patent is projected to issue on August 25, 2009, but it may issue earlier or later depending on the circumstances of publication. However, even assuming *arguendo* that a patent is issued on the same day as the date Applicants pay the issue fee (*i.e.*, May 14, 2009), said issue date would be 4 years and 155 days after the date on which the above-referenced application was filed under 35 U.S.C. § 111(a). As none of the exclusionary periods set forth in 37 C.F.R. § 1.702(b) apply to the instant application and in accordance with 37 C.F.R. § 1.703, a minimum period of examination delay is calculated to be at least 520 days, based on the hypothetical issue date of May 14, 2009. This minimum period of examination delay is to be extended by an additional term equal to the number of days following May 15, 2009 to the date of issuance of a patent. Accordingly, the entire period of Three Years Delay is the sum of the minimum period of examination delay of 520 days and the number of days from May 15, 2009, to the day of issuance of a patent.

(iii) Total Examination Delay Pursuant to 37 C.F.R. § 1.703(f)

As set forth in 37 C.F.R. § 1.703(f), the period of examination delay based on the grounds set forth in 37 C.F.R. § 1.702 is the sum of the period of 14 Month Delay (593 days) and the minimum period of Three Years Delay (520 days), or 1113 days, to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on September 26, 2007, prior to the first day of the period of Three Years Delay, *i.e.*, December 11, 2007, Applicants submit that these periods are not overlapping.

B. “Applicant Delay” Pursuant to 37 C.F.R. § 1.704

Pursuant to 37 C.F.R. § 1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As indicate on the PTAS Sheet (Exhibit A), the Office has calculated a period of Applicant Delay of 124 days.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 C.F.R. § 1.702(f)

As set forth in 37 C.F.R. § 1.702(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is at least 989 days, which is the difference between the total period of examination delay (1113 days) and the period of Applicant Delay (124 days). Applicants further submit that the term of 988 days should be extended by an additional term equal to the number of days following payment of the issue fee, to the date of issuance of a patent for the above-referenced application in accordance with 37 C.F.R. § 1.703(b). **As such, the correct patent term adjustment upon issuance of a patent is expected to be the sum of 988 days (as calculated herein) plus the number of days from May 15, 2009, to the issuance of a patent.**

4. In accordance with 37 C.F.R. § 1.705(b)(2)(iii), Applicants submit that any pending patent corresponding to this application is not subject to any terminal disclaimer.

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of 989 days, with an additional term to be added based on the number of days following payment of the issue fee on May 14, 2009, to the date of issuance of a patent for the above-referenced application.

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